REMARKS

I. Status of the Claims

Claims 31-38, 40-54, and 56-66 remain pending in this application. Claim 31 has been amended to correct a typographical error. Accordingly, no issue of new matter is raised by this Amendment.

II. Rejection Under 35 U.S.C. § 103(a)

Claims 31-38, 40-54, and 56-66 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,716,625 (Hahn) in view of U.S. Patent No. 5,358,969 (Williamson), U.S. Patent No. 5,449,688 (Wahl), or the combination of Williamson and Wahl. Applicant respectfully traverses this rejection.

In order to establish a *prima facie* case of obviousness, the Office must satisfy three criteria. The Office must demonstrate (1) that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings of the references in the manner suggested by the Office, (2) that there is a reasonable expectation of success in the proposed modification or combination, and (3) that the prior art references teach or suggest all claim limitations. *See* M.P.E.P. § 2143. If the Office does not show that all of these criteria have been met, the Office has not met its burden, and a *prima facie* case of obviousness has not been established. Applicant

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

submits that these criteria have not been satisfied in the present case, and thus, the rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

The Federal Circuit has held that the suggestion or motivation to modify or combine the references must come from the references themselves or from the knowledge of one of ordinary skill in the art, but may not flow from an applicant's disclosure. *See In re Fine,* 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996); *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Importantly, the evidence of a suggestion or motivation to combine must be "clear and particular." *See In re Dembiczak*, 175 F.3d 994, 999 (Fed Cir. 1999). Broad conclusory statements regarding the teachings of multiple references, standing alone, are not evidence. *Id.* In the present case, not only is there no motivation in the references cited to make the modification or combination proposed by the Office, but in fact, the only way that the Office could have concluded that the claimed invention was obvious was by using impermissible hindsight. Thus, the rejection under 35 U.S.C. § 103(a) is improper and should be reversed.

According to the Office, Hahn teaches the general theory of combining an irritant with an anti-irritant. *See* page 3, lines 10-11 of the April 19, 2000 Office Action. As the Office has acknowledged, however, Hahn teaches the use of specifically the strontium (II) cation as an anti-irritant. *See* page 3, lines 11-13 of the April 19, 2000 Office Action.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

There is no suggestion in Hahn, nor has the Office pointed to any, that would have motivated the skilled artisan, viewing the reference, to replace the strontium cation with another anti-irritant. Furthermore, the teachings of Hahn are not generic with respect to anti-irritants, and thus, do not suggest its substitution. Apparently recognizing this deficiency of Hahn, the Office relies on either Williamson, Wahl, or the combination of the two, to supply the motivation for substituting the strontium cation with another anti-irritant. This argument has at least two major flaws, however, and therefore cannot support a finding of *prima facie* obviousness.

First, the Office's argument improperly fails to consider the teachings of the references "as a whole." A reference must be considered for everything it teaches, and not just that which will support a given position to the exclusion of other parts necessary to the full appreciation of what the reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 353 F.2d 238, 241, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965); *see also Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-49, 230 U.S.P.Q. 416, 420 (Fed. Cir. 1986) (holding that district court, by failing to consider a prior art reference in its entirety, ignored portions of the reference that led away from obviousness).

Specifically, both Wahl and Williamson disclose anti-inflammatory compositions, whereas Hahn is an anti-irritant formulation. Notably, Hahn teaches that anti-inflammatory agents and anti-irritants are not interchangeable, stating that "[a]gents

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

which are effective to combat one source of sensory stimulus-for example steroidal agents to treat skin inflammation-are ineffective against other sensory stimuli such as pressure, heat, or the transitory sting or itch caused by an applied skin care product." *See* column 8, lines 55-60. Thus, in view of the **entire** teaching of Hahn, one of ordinary skill in the art would not have been motivated to combine the references and substitute the anti-inflammatory agents of Williamson or Wahl for the anti-irritant of Hahn.

Second, the Office's argument demonstrates that, at most, one of ordinary skill in the art would have been motivated to try innumerable anti-irritants in the compositions of Hahn. *See* page 4, lines 1-3 of the April 19, 2000 Office Action, where the Office states that "it is the opinion of the Examiner that a skilled artisan would have been motivated to incorporate any anti-irritant in place of the strontium cation in the teachings of Hahn, and still be able to counteract the irritation." However, as the Office is aware, "obvious to try" is a legally improper standard for determining obviousness. *See In re Fine,* 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988) (stating that "whether a particular combination might be 'obvious to try' is not a legitimate test of patentability.").

In direct rebuttal of the Office's statement, Applicant points out that Hahn teaches that the effect of any particular agent on nerve activity and sensation in intact human bodies is very difficult to predict. *See* column 6, lines 55-58. Thus, the skilled

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

artisan would have no reasonable expectation that "any anti-irritant" would be successful in the compositions of Hahn, and in fact, would expect to perform significant experimentation and encounter great difficulty in determining which anti-irritants would provide the desired anti-irritant effect.

Accordingly, it is Applicant's position that the Office has used impermissible hindsight, after viewing the present disclosure, to make its determination of obviousness over Hahn in view of Williamson, Wahl, or the combination of the two, because Hahn's teaching of the unpredictability of the various agents along with the non-interchangeability of anti-irritants and anti-inflammatory agents actually teaches away from the modification or combination suggested by the Office. In view of the teachings of the cited references, as set forth above, the skilled artisan would not have arrived at the presently claimed invention after viewing the references, without having the present disclosure as a blueprint. Accordingly, the Office has failed to establish any suggestion or motivation in the references themselves, and thus, the rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

III. Conclusion

In view of the foregoing amendment and remarks, Applicant respectfully requests prompt reconsideration and timely allowance of the pending claims.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

If there are any other fees due in connection with this filing, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____
Michelle E. O'Brien
Reg. No. 46,203

Date: July 13, 2000

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000